

XII. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

November 16, 2004

1. Submission Applicant & Correspondent:

Name: Osteotech, Inc.
 Address: 51 James Way
 Eatontown, NJ 07724
 Phone No.: (732) 542-2800
 Contact Person: Chris Talbot

2. Name of Product:

Trade/Proprietary/Model Name: VIAGRAF[◇] DBM Paste
 Common or Usual Name: Demineralized Bone Matrix Allograft
 Classification Name: Resorbable Bone Void Filler

3. Devices to Which New Product is Substantially Equivalent:

VIAGRAF[◇] DBM Paste is substantially equivalent, for the purpose of this 510(k), to the following predicate devices.

<u>Trade/Proprietary/Model Name</u>	<u>Manufacturer</u>	<u>510(K) #</u>
Exactech Resorbable Bone Paste	Exactech	K020078
Exactech Resorbable Room Temperature Bone Paste	Exactech	K040755
Allomatrix Putty	Wright Medical	K020895
Allomatrix Putty	Wright Medical	K041186

4. Device Description:

VIAGRAF[◇] DBM Paste is an osteoconductive human bone allograft product consisting of human demineralized bone matrix (DBM) to which an inert starch-based carrier has been added. It is intended for use in filling bony voids or gaps of the extremities not intrinsic to the stability of the bony structure. VIAGRAF[◇] DBM Paste is provided in a ready-to-use paste-like, malleable form that can be molded or manipulated by the user into various shapes. It is provided in various package sizes by volume.

5. Intended Use/Indications

VIAGRAF[◇] DBM Paste is intended for use in filling bony voids or gaps of the extremities that are not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury

to the bone. VIAGRAF[◇] DBM Paste is resorbed/remodeled and is replaced by host bone during the healing process.

6. Technical Comparison

VIAGRAF[◇] DBM Paste is substantially equivalent to one or more of the predicate devices with respect to materials in that it consists of human demineralized bone matrix (DBM) and an inert resorbable non-tissue additive or carrier. It is provided in a ready-to-use paste-like, malleable form that can be molded or manipulated by the user into various shapes.

7. Performance Data

The results of bone formation studies in animal models demonstrated acceptable bone formation with VIAGRAF[◇] DBM Paste. In addition, relevant clinical data exists that supports the performance of VIAGRAF[◇] DBM Paste.

8. Viral Inactivation

VIAGRAF[◇] DBM Paste is produced by a proprietary production process that has been validated to inactivate viruses including: HIV-1; hepatitis B virus (duck hepatitis virus as model); hepatitis C virus (bovine diarrhea virus as model), CMV; and Polio virus. This process is used to further reduce the risk of disease transmission via the use of this product beyond the protection provided by donor testing and screening procedures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 5 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Christopher Talbot
Director, Regulatory Affairs
Osteotech, Inc.
51 James Way
Eatontown, NJ 07724

Re: K043209
VIAGRAF® DBM Paste
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: October 27, 2005
Received: October 28, 2005

Dear Mr. Talbot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


s/ Mark N. Melkerson.

Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use – Statement

510(k) Number (if known): K043209

Device Name: VIAGRAF[◇] DBM Paste

Indications for Use:

VIAGRAF[◇] DBM Paste is intended for use in filling bony voids or gaps of the extremities that are not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone. VIAGRAF[◇] DBM Paste is resorbed/remodeled and is replaced by host bone during the healing process.

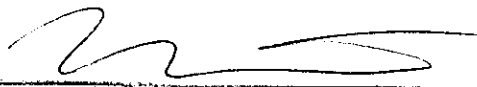
Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043209